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09/754,010	01/03/2001	Mark E. Dillon	E-1950	3438

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 06/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/754,010

Applicant(s)

DILLON, MARK E.

Examiner

Sharmila S. Gollamudi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-23, 25, 26 and 29-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-23, 25, 26 and 29-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt of Request for Continued Examination and Amendments filed 12/27/04 and the Petition Decision of 3/31/05 is acknowledged. Claims 18-23, 25-26, and 29-33 are pending in this application. Claims 1-17 stand cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18, 20, 22, 26, and 31-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 recites the limitation "at least one second layer" in line 7. There is insufficient antecedent basis for this limitation in the claim.

Claim 20 is directed to a bonding agent for bonding the first layer and second layer, which is indefinite since it is unclear where this bonding agent is located or does the bonding agent make a separate layer itself? Further clarification is requested.

Claim 22 is directed to the first layer comprises "at least one membrane layer", this is vague since it is unclear if this membrane layer is a separate layer from the "first layer" or is it the first layer. Further clarification is requested. For examination purposes, the examiner will apply both interpretations, i.e. the membrane layer is a separate layer from the first layer and the membrane layer is the first layer.

Claim 31 is directed to a substantially transparent first layer wherein the said first layer comprises a pigment for imparting a "discernable color" to the first layer, which is vague and

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indefinite. It is unclear if the first layer is transparent or has a discernable color since both are contradictory limitations.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 18-21, 22-23, 25, 29, and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Lindqvist et al (6,015,747).

Lindqvist et al disclose a wound dressing comprising a gel layer (3) and a polyurethane foam layer with open cells (fenestrations) (2). See Figure 2. The gel layer is made of a skin adhering silicone gel (polydimethylsiloxane gel). See column 5, lines 45-65. Figure 1 discloses a gel layer (3), a polyurethane foam layer with open cells (2), and a liquid impervious layer made of a polyurethane film (5) (membrane layer). See column 22, line 65 to column 3, line 2.

It should be noted that it is the examiner's position that the silicone gel also acts as the "bonding agent" since the gel binds to the foam. Further, it should be noted that polydimethylsiloxane is a substantially transparent gel (See US 4929211 column 3, lines 35-40 as art of interest) and thus the foam is substantially opaque compared to the gel layer. It should be noted that membrane is defined as a "thin, soft pliable sheet or layer"; thus Hofeditz polymeric gel layer reads on claim 22. Lastly, it should be noted that claim 31 is rejected in instant rejection since the claim is indefinite with two contrary limitations for the first layer, i.e.

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it is transparent and it is pigmented. Thus, claim 31 is rejected with reference to the first layer being transparent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18-20, 22, 25, 29, 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Hofeditz et al (4,552,138).

Hofeditz et al disclose a dressing material comprising at least one layer of hydrophilic, transparent polymeric gel and a carrier material. Example 5 discloses the gel layer laminated to an open-pore (fenestrations) polyurethane foam.

It should be noted that it is the examiner's position that Hofeditz foam layer will be substantially opaque compared to the transparent gel layer and thus meets the claim limitation of claim 31. Further, it should be noted that claim 31 is rejected in instant rejection since the claim is indefinite with two contrary limitations for the first layer, i.e. it is transparent and it is pigmented. Thus, claim 31 is rejected with reference to the first layer being transparent. It should be noted that membrane is defined as a "thin, soft pliable sheet or layer"; thus Hofeditz polymeric gel layer reads on claim 22. Lastly, it should be noted that the gel is tacky and binds to the foam and thus acts as the "bonding agent".

Claims 18-20, 22, 25, 29, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Freeman (5,681,579).

Freeman discloses a polymeric support wound dressing which comprises a occlusive layer and a support layer. See abstract. Figure 1 discloses the occlusive layer (11) (second layer) is preferably a polyurethane foam bonded by adhesives means to a perforated film (12) (first layer). See also column 4 to column 5 and examples. Dressing A discloses a hydrocolloid

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centered on a polyurethane foam which is adhered to a perforated polyurethane perforated film.

See column 10, lines 20-45.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 26 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindqvist et al (6,015,747) in view of Lorenz et al (5,258,421).

Lindqvist et al disclose a wound dressing comprising a gel layer (3) and a polyurethane foam layer with open cells (fenestrations) (2). See Figure 2. Figure 1 discloses a gel layer (3), a polyurethane foam layer with open cells (2), and a liquid impervious layer made of a polyurethane film (5) (membrane layer). See column 22, line 65 to column 3, line 2. The gel layer is made of a skin adhering silicone gel. See column 5, lines 45-65. Note the silicone gel also acts as the bonding agent. It should be noted that silicone gels are substantially transparent.

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Lindqvist does not teach the use of instant silicone-polytetrafluoroethylene IPN membrane layer. Lindqvist also does not teach the use of a pigment in the gel layer.

Lorenz et al teaches a hydrophilic gel dressing (Note abstract). The dressing is made of a tacky gel of polyurethane and poly (N-vinyl lactam) on a substrate. Lorenz teaches coating the gel layer on a backing substrate that provides liquid barrier properties and may be a polymer film such as polyurethane. The polymer film may also be silicone-polytetrafluoroethylene IPN membrane. Lorenz teaches silicone-polytetrafluoroethylene has particular utility in wound dressing because it keeps moisture in and excess exudate is absorbed to promote healing. See column 5, lines 50-68. When the backing substrate is of the instant silicone-polytetrafluoroethylene, the structure is also useful as a burn blanket. See 5, lines 30-33 and column 6, lines 28-30. Additionally, the backing substrate may be covered by a silicone-coated release-liner. Additionally, Lorenz teaches the use of various conventional additives such as pigments and dyes in the gels. See column 4, lines 49-55.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Lindqvist et al and Lorenz et al and replace Lindqvist's polyurethane polymer film with the instant silicone-polytetrafluoroethylene IPN polymer film. One would have been motivated to do so since Lorenz teaches that both polyurethane films and the instant film have barrier properties; however the instant IPN polymer film provides certain advantages for wound and burn dressing by keeping the moisture in, preventing bacteria from entering the wound and absorbing the excess exudates, thereby promoting healing. Therefore, a skilled artisan would have been motivated to utilize the instant polymer film in Lindqvist's

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wound dressing if one desired to provide a structure that also promoted healing by preventing re-infection, i.e. by preventing bacteria from entering the wound site.

Additionally, it would have been obvious to add a pigment to the silicone gel of Lindqvist if one desired for an article with a gel layer with a distinct layer. It should be noted that the instantly claimed aesthetic design change does not impart patentable significance with regard to the mechanism in which the wound article functions. Lastly, it should be noted that claim 31 is rejected in instant rejection since the claim is indefinite with two contrary limitations for the first layer, i.e. it is transparent and it is pigmented. Thus, claim 31 is rejected with reference to the first layer being pigmented.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lindqvist et al (6,015,747) in view of Lorenz et al (5,258,421) in further view of Cartmell et al (5,160,328).

The teachings of Lindqvist et al and Lorenz et al have been set forth above.

The references do not teach the use of fenestrations in the layer.

Cartmell teaches a hydrogel bandage for wounds. Cartmell teaches that the bandage is formed from materials which permit the transmission of air and vapor so as to facilitate further the healing of the wound. Cartmell teaches that the materials may also be perforated or scored with holes or apertures to readily permit the passage of air and vapor. In this way, bacterial proliferation and the formation of incrustations in the wound are minimized. See column 5, lines 35-45.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the teachings of Lindqvist et al, Lorenz et al, and Cartmell et al and

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perforate the layers of the device. One would have been motivated to do so since Cartmell teaches the passage of air and vapor is crucial for the healing process and by perforating the layers, bacterial proliferation and incrustations are prevented. Therefore, a skilled artisan would have been motivated to perforate the layers to further contribute to the healing process.

Claims 23 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman (5,681,579) in view of Lorenz et al (5,258,421).

Freeman discloses a polymeric support wound dressing which comprises an occlusive layer and a support layer. See abstract. Figure 1 discloses the occlusive layer (11) (second layer) is preferably a polyurethane foam bonded by adhesive means to a perforated film (12) (first layer). See also column 4 to column 5 and examples. Dressing A discloses a hydrocolloid centered on a polyurethane foam which is adhered to a perforated polyurethane perforated film. See column 10, lines 20-45.

Freeman does not teach the use of instant silicone-polytetrafluoroethylene IPN membrane layer.

Lorenz et al teaches a hydrophilic gel dressing (Note abstract). The dressing is made of a tacky gel of polyurethane and poly (N-vinyl lactam) on a substrate. Lorenz teaches coating the gel layer on a backing substrate that provides liquid barrier properties and may be a polymer film such as polyurethane. The polymer film may also be silicone-polytetrafluoroethylene IPN membrane. Lorenz teaches silicone-polytetrafluoroethylene has particular utility in wound dressing because it keeps moisture in and excess exudate is absorbed to promote healing. See column 5, lines 50-68. When the backing substrate is of the instant silicone-polytetrafluoroethylene, the structure is also useful as a burn blanket. See 5, lines 30-33 and

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column 6, lines 28-30. Additionally, the backing substrate may be covered by a silicone-coated release-liner. Additionally, Lorenz teaches the use of various conventional additives such as pigments and dyes in the gels. See column 4, lines 49-55.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Freeman and Lorenz et al and replace Freeman's polyurethane polymer film with the instant silicone-polytetrafluoroethylene IPN polymer film. One would have been motivated to do so since Lorenz teaches that both polyurethane films and the instant film have barrier properties; however the instant IPN polymer film provides certain advantages for wound and burn dressing by keeping the moisture in, preventing bacteria from entering the wound and absorbing the excess exudates, thereby promoting healing. Therefore, a skilled artisan would have been motivated to utilize the instant polymer film in Lindqvist's wound dressing if one desired to provide a structure that also promoted healing by preventing re-infection, i.e. by preventing bacteria from entering the wound site.

Duplicate Claims

Applicant is advised that should claim 25 be found allowable, claim 29 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Conclusion

None of the claims are allowed at this time.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616

SSG

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